

EXHIBIT 21



Prescribing Policies: States Confront Opioid Overdose Epidemic

6/30/2019

Overview



Responsible for 115 deaths each day, the opioid epidemic continues to devastate the nation. The death rate from these drugs has nearly quadrupled since 1999, and continues to rise. Nearly half of these opioid-related deaths—46 each day—involved a prescription opioid, according to the Centers for Disease Control and Prevention.

Prescription opioids (e.g., oxycodone, hydrocodone, methadone) are used to treat moderate to severe pain, and can provide effective pain management when prescribed and taken as directed. However, prescription opioids can also be misused and lead to addiction, death, job loss and a host of other problems, taking a significant human and financial toll on individuals, families, communities and states.

State lawmakers are crafting innovative policies—engaging health, criminal justice, human services and other sectors—to address this public health crisis while also ensuring appropriate access to pain management. This report provides an overview of state legislation setting guidelines for, or limits on, opioid prescriptions. As of October 1, 2018, at least 33 states have enacted legislation related to opioid prescription limits.

[Background](#)[State Action](#)[Table: Legislation](#)

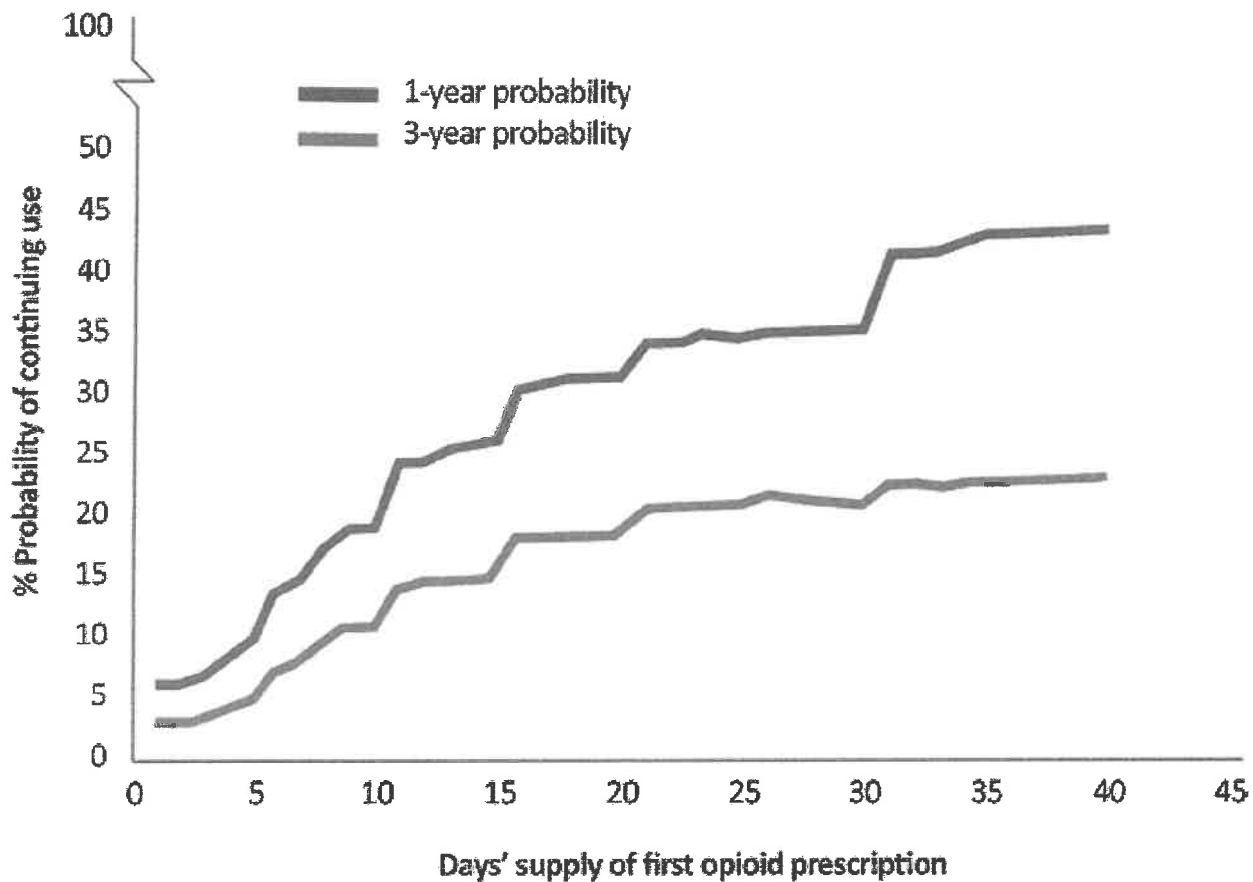
The opioid epidemic is fueled by misuse of prescription and illicit opioids (e.g., heroin and fentanyl). Research indicates that the majority of illicit users first misused prescription opioids. According to the Centers for Disease Control and Prevention (CDC), there has been a significant increase in opioid prescriptions for pain since 1999, while the amount of pain that Americans report has not changed much overall. While new research found that the amount of opioids prescribed decreased between 2010 and 2015, it remains about three times higher than in 1999.

In response to the epidemic, the CDC released the “Guideline for Prescribing Opioids for Chronic Pain” in March 2016. The guideline offers primary care providers a set of voluntary, evidence-based recommendations for prescribing opioids to patients 18 years or older in primary care settings. It focuses on chronic pain treatment, and does not apply to patients in active cancer treatment, palliative care or end-of-life care. The recommendations are based on existing scientific evidence. For example, higher doses of opioids are associated with higher risk of overdose and death. Even relatively low dosages—considered to be 20 to 50 morphine milligram equivalents (MME) per day—increase risk. As such, the guideline recommends starting with the lowest effective dosage, and carefully considering dosages above 50 or 90 MMEs per day. For treating acute pain, the guideline recommends a quantity no greater than what is needed for the expected duration of pain severe enough to require opioids, specifying that three days or less will often be sufficient and more than seven days will rarely be needed.



Using opioids to treat acute pain can lead to long-term use. The likelihood of long-term use increases based on the length of the initial prescription, according to the CDC. In fact, the likelihood of long-term use increases sharply after the third and fifth days of taking a prescription, and spikes again after the 31st day. According to the CDC, long-term use also increases with a second prescription or refill, a 700 morphine milligram equivalents (MME) cumulative dose, and an initial 10- or 30-day supply.

Improving prescribing practices and the way pain is treated is one avenue to help prevent misuse, addiction and overdose, while ensuring legitimate access to pain management. In recent years, a number of states have enacted policies related to prescribing opioids, some of which align with certain recommendations in the CDC Guideline.



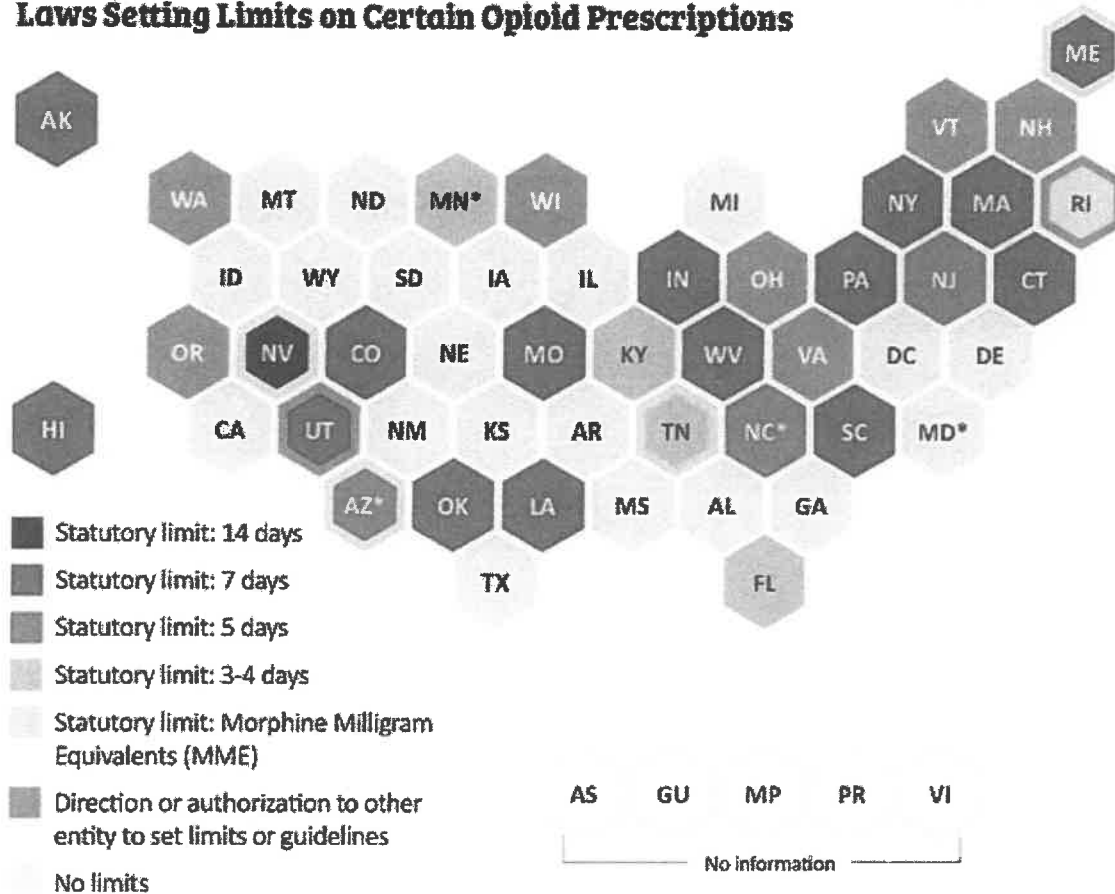
Source: Centers for Disease Control and Prevention, 2017

State Legislation

Legislation limiting opioid prescriptions debuted early in 2016, with Massachusetts passing the first law in the nation. Among other provisions in the comprehensive act, the state set a seven-day supply limit for initial (first-time) opioid prescriptions. Prior to Massachusetts' law, some states had passed bills related to prescribing, such as Washington's legislation directing five professional boards and commissions to adopt rules related to chronic, non-cancer pain management, but none had set such a short time limit in statute.

By the end of 2016, seven states had passed legislation limiting opioid prescriptions, and the trend continued in 2017. More than 30 states considered at least 130 bills related to opioid prescribing in 2016 and 2017. According to NCSL's tracking, 33 states had enacted legislation with some type of limit, guidance or requirement related to opioid prescribing by October 2018.

Laws Setting Limits on Certain Opioid Prescriptions



* Note: The map displays the state's primary opioid prescription limit and does not include additional limits on certain providers or in certain settings. Arizona allows prescriptions up to 14 days following surgical procedures and North Carolina allows up to seven days for post-operative relief. Maryland requires the "lowest effective dose." Minnesota's limit is for acute dental or ophthalmic pain. The map also does not reflect limits for minors that exist in at least eight states.

Source: NCSL, StateNet

Most of this legislation limits first-time opioid prescriptions to a certain number of days' supply—seven days is most common, though some laws set limits at three, five or 14 days. In a few cases, states also set dosage limits (morphine milligram equivalents, or MMEs). Nearly half the states with limits specify that they apply to treating acute pain, and most states set exceptions for chronic pain treatment.

In addition to exceptions for chronic pain, most laws also exempt treatment for cancer and palliative care from prescription limits. Many also allow exceptions for the treatment of substance use disorder or medication-assisted treatment (MAT), or for the professional judgment of the provider prescribing the opioid. Many laws stipulate that any exceptions must be documented in the patient's medical record.

While the majority of states focus on general opioid prescribing, Alaska, Connecticut, Indiana, Louisiana, Massachusetts, Nebraska, Pennsylvania and West Virginia also set limits specifically for minors. These laws set limits for any opioid prescription (versus the initial opioid prescription for adults) and may also specify other requirements, such as discussing opioid risks with the minor and parent or guardian.

Rather than setting opioid prescription limits in statute, a few state laws direct or authorize other entities to do so (such as New Hampshire, Ohio, Oregon, Vermont, Virginia, Washington and Wisconsin). These entities may include the department of health/state health official, or provider

regulatory boards such as the board of medicine, nursing and/or dentistry. Other states, such as Rhode Island and Utah, have prescribing limits in statute, and allow other entities to adopt prescribing policies.

In addition, state laws—such as those in Maryland and Utah—may provide guidance or direction related to opioid prescribing. Maryland's law requires providers to prescribe the lowest effective dose of an opioid for a quantity that is not greater than that needed for the expected duration of pain. Utah, in addition to its seven-day prescribing limit, authorizes commercial insurers, the state Medicaid program, workers' compensation insurers and public employee insurers to implement policies for prescribing certain controlled substances. The policies must include evidence-based guidelines for prescribing opioids.

Other State Strategies

In addition to prescribing policies, state leaders are tackling prescription drug misuse with various approaches. When attempting to prevent or intervene early in misuse, addiction and overdose, states have enacted numerous laws related to prescription drug monitoring programs, access to naloxone, pain clinic regulation, provider education and training, and other topics. NCSL tracks these bills in the Injury Prevention Database, which follows six categories of legislation aimed at preventing prescription opioid misuse. The database cataloged more than 1,300 bills on these topics from 2015 to 2017.

Prescription drug monitoring programs (PDMPs) are one of the strategies with the most evidence backing their effectiveness to improve opioid prescribing and protect patients. In recent years, states have enacted bills to mandate PDMP registration for providers, determine who can access the PDMP on behalf of prescribers, set the length of time within which to report dispensing of prescriptions, establish requirements for checking the PDMP before prescribing, and more.

Naloxone is a medication that can reverse an opioid overdose. In addition to laws providing immunity for carrying, dispensing and/or administering naloxone, lawmakers have been increasing access to naloxone. For example, states have allowed third-party prescriptions, naloxone standing orders and pharmacists to dispense naloxone without a prescription. Other laws have expanded who is allowed to carry and use naloxone, such as family and friends, school personnel, law enforcement and emergency/first responders.

State legislators have also considered legislation related to pain clinics—facilities that specialize in treating chronic pain. Pain clinic laws often focus on licensing, regulation or other requirements. If pain clinics prescribe pharmaceuticals based primarily on financial gain rather than medical need, it can lead to over-prescribing and misuse of prescription drugs. These laws have been shown to be effective in states that identified an issue with certain pain clinics.

States have also created requirements for training or education for providers related to opioids, such as training in prescribing controlled substances, pain management and identifying substance use disorders.

Conclusion

State legislators, health care providers, patients and families continue to confront the opioid epidemic with various strategies. It remains a challenge to treat pain and ensure access to effective treatments, while also preventing misuse, addiction and death. In the past few years, state leaders in at least 33 states have adopted guidelines, limits or other requirements for prescribing opioids. These new policies are among the numerous strategies that are being tested as leaders search for solutions to the epidemic.

State Prescribing Legislation

This table summarizes the limitations for opioid prescriptions recently made in state legislation, as of April 4, 2018. It does not include the laws in New Hampshire, Ohio, Oregon, Rhode Island, Utah, Vermont, Virginia, Washington and Wisconsin that authorize other entities to set prescribing limits or guidelines.

State Prescribing Legislation

State and Bill Number (Year Enacted)	Number of Days or MME*	Limitations/ Requirements	Exceptions to Number of Days/MME						
			Chronic Pain	Cancer	Palliative Care	Hospice Care	Provider Judgment	SUD / MAT**	Other
Alaska HB 159 (2017)	7 days	Initial prescription for adult Any prescription for minor	x	x	x		x	x	Patient travel or logistical barrier
	4 days	Initial prescription for adult when prescribed by an optometrist Any prescription for minor when prescribed by an optometrist							
Arizona SB 1001a (2018)	5 days	Initial prescription		x	x	x	x	x	Traumatic injury Skilled nursing facility care Burn treatment Infant being weaned off opioids at time of discharge (day exception only) Hospitalization (MME exception only)
	14 days 90 MME/day	Following surgical procedure New prescription							
Connecticut HB 5053 (2016) HB 7052 (2017)	7 days	Initial prescription for adult	x	x	x		x	x	
	5 days	Any prescription for minor							

State and Bill Number (Year Enacted)	Number of Days or MME*	Limitations/ Requirements	Exceptions to Number of Days/MME						
			Chronic Pain	Cancer	Palliative Care	Hospice Care	Provider Judgment	SUD / MAT**	Other
Florida HB 21 (2018)	3 days	Prescription for acute pain							7-day supply permitted if medically necessary based on provider professional judgment Definition of acute pain excludes: cancer, terminal conditions, traumatic injury, and palliative care Exceptions in dispensing provisions allow for MAT
Hawaii SB 505 (2017)	7 days	Initial concurrent prescriptions of opioids and benzodiazepines	x	x	x	x		x	Post-operative care
Indiana SB 226 (2017)	7 days	Initial prescription for adult Any prescription for minor		x	x		x	x	Adopted by medical licensing board rule
Kentucky HB 333 (2017)	3 days	Initial prescription of Schedule II controlled substance for acute pain	x	x		x	x	x	Inpatient setting Major surgery or trauma Determined by licensing board in consultation with state Office of Drug Control Policy
Louisiana HB 192 (2017)	7 days	Initial prescription for adult for acute pain Any prescription for minor	x	x	x		x	x	

State and Bill Number (Year Enacted)	Number of Days or MME*	Limitations/ Requirements	Exceptions to Number of Days/MME						
			Chronic Pain	Cancer	Palliative Care	Hospice Care	Provider Judgment	SUD / MAT**	Other
Maine SB 671 (2016) SB 338 (2017)	100 MME/day 7 within 7 days OR 30 within 30 days	Acute pain Chronic pain		x	x	x		x	Determined by dept. of health ER, inpatient hospital setting, long-term care facility or residential care facility Surgical procedures
Maryland HB 1432 (2017)	Requires providers to prescribe lowest effective dose of an opioid and a quantity that is not greater than needed for the expected duration of pain		x	x	x	x		x	
Massachusetts HB 4056 (2016)	7 days	Initial prescription for adult Any prescription for minor	x	x	x		x	x	
Minnesota SF 2a (2017)	4 days	Schedule II through IV controlled substances when used for acute dental or ophthalmic pain	x	x	x	x	x		
Nebraska LB 931 (2018)	7 days	Prescription for minor for acute pain		x	x		x		
Nevada AB 474 (2017)	14 days 90 MME/day	Initial prescription of Schedule II through IV controlled substances for acute pain MME limit for opioid that has never been issued to patient before or has been issued more than 19 days prior							

State and Bill Number (Year Enacted)	Number of Days or MME*	Limitations/ Requirements	Exceptions to Number of Days/MME						
			Chronic Pain	Cancer	Palliative Care	Hospice Care	Provider Judgment	SUD / MAT**	Other
New Jersey SB 3 (2017)	5 days	Initial prescription for acute pain Requires "lowest effective dose" of opioid for any prescription for acute pain		x	x	x		x	Long-term care facility
New York SB 8139 (2016)	7 days	Initial prescription for adult	x	x	x	x			
North Carolina HB 243 (2017)	5 days	Initial prescription for certain Schedule II and III controlled substances for acute pain	x	x	x	x		x	Administered in hospital, nursing home or residential care facility
	7 days	Prescription for certain Schedule II and III controlled substances for post-operative relief							
Pennsylvania SB 1367 (2016) HB 1699 (2016)	7 days	Prescription in ER, urgent care, hospital observation Any prescription for a minor	x	x	x	x	x		
Rhode Island SB 2823 (2016) HB 8224 (2016)	30 MME/day	Up to 20 doses for initial prescriptions for adults for acute pain	x	x	x			x	Dept. of health regulations
Utah HB 50 (2017)	7 days	Prescription for Schedule II and III opioids for acute pain	x						Surgery (permits up to 30 days) Complex or chronic conditions

State and Bill Number (Year Enacted)	Number of Days or MME*	Limitations/ Requirements	Exceptions to Number of Days/MME						
			Chronic Pain	Cancer	Palliative Care	Hospice Care	Provider Judgment	SUD / MAT**	Other
West Virginia SB 273 (2018)	7 days 3 days	Initial prescription for "lowest effective dose" Prescription for minor Also: 3-day supply written by a dentist or optometrist 4-day supply of an opioid for outpatient use for an adult seeking care in an emergency room or urgent care		x	x	x		x	Long-term care facility 7-day supply permitted in urgent care if medical rational is documented

*Morphine milligram equivalents (MME)

**SUD/MAT denotes exceptions for treatment of substance use disorder (SUD) or medication-assisted treatment (MAT).

Note: The table summarizes the enacted legislation and the changes made to existing law. For a more comprehensive look at how states handle prescription drug limits, view the full statutory language.

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